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Massachusetts Board of Registration in Pharmacy

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1. New Board Member Appointments

The Massachusetts Board of Registration in Pharmacy is pleased to announce Governor Mitt Romney's recent appointment of Nurse Member Kathy J. Fabiszewski, PhD, RN, to a five-year term. Dr Fabiszewski currently practices as a nurse practitioner in a group practice, where she specializes in gerontology, and is an assistant professor of nursing at Salem State College. In her spare time she serves her country as a lieutenant colonel in the United States Army Reserves, where she recently completed a tour of active duty in Iraq. While serving the military, Kathy continues to be adjunct professor at the US Army, Command and General Staff College, in Fort Leavenworth, KS.

2. Board Position Promotion Announcement

Samuel J. Penta, RPh, Board investigator, was recently promoted to supervisor of health care investigators. Sam will continue to investigate, but will supervise investigators responding to consumer complaints of medication errors and reports of drug diversion, substance abuse, and other violations of Board of Pharmacy Regulations. In addition, he will continue to oversee and carry out inspections of community pharmacies, nuclear pharmacies, wholesale distributors, and other licensed premises.

3. Letter from the President

By Karen Ryle, RPh, MS, President

As I start off my year as president, I would like to take this opportunity to thank Jim DeVita for the outstanding job he did as president of the Board in 2004. It is truly a pleasure to work with someone who has such a passion for pharmacy.

As I reflect on what the most important role for the president of the Board is, I look toward the Board's mission statement:

> To promote, preserve, and protect the public health, safety, and welfare by fostering the provision of quality pharmaceutical care to the citizens of Massachusetts through the regulation of the practice of pharmacy, the operation of pharmacies, and the distribution of prescription drugs in the public interest. The Massachusetts Board of Registration [in] Pharmacy will assume a leadership role in regulating the practice of pharmacy and act in accordance with the highest standards of ethics, accountability, efficiency, effectiveness, and openness.

With patient safety in mind, the Board's strategic plan for 2005 will include revision of wholesale distributor regulations to protect the public from the threat of counterfeit drugs, review of compounding requirements, and education of licensees regarding the establishment of continuous quality improvement (CQI) program requirements of 247 CMR 15.00, implementation of CQI programs in pharmacies licensed by the Board by December 31, 2005.

I recently had the pleasure of serving as chairman for the National Association of Boards of Pharmacy®'s (NABP®) Task Force to Develop Recommendations to Best Reduce Medication Errors in Community Pharmacy Practice. The Task Force included members of various state boards of pharmacy, a member of the Institute for Safe Medication Practices, and a member of the Joint Commission on Accreditation of Healthcare Organizations. It is amazing what can be accomplished when you have such dedicated people that share the same goal of increased patient safety. I am excited about sharing those recommendations to the pharmacists of Massachusetts when they become available to the public.

I look forward to the upcoming year as president and will enjoy working with various professionals to advance the practice of pharmacy.

4. Pharmacy Technician Update

To date, the Board has registered 6,280 pharmacy technicians, many of whom are also certified by the Pharmacy Technician Certification Board (PTCB). PTCB's governing organizations are the American Pharmacists Association, the

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Accutane, Palladone RMPs Designed to Protect Patient Safety

Risk Management Programs (RMPs) are developed by drug manufacturers to meet the requirements of FDA's drug approval process, in conjunction with FDA, to minimize risks associated with specific drug products. To date, several specific drug products have formal risk management programs beyond labeling alone, to further ensure patient safety. Two relevant examples are Accutane® (Roche Pharmaceuticals) and Palladone Capsules (Purdue Pharma LP).

Accutane

On November 23, 2004, FDA announced changes to the RMP for isotretinoin (Accutane) that will be implemented in mid-2005 in order to reduce the risk of birth defects associated with fetal exposure to the medication. All of the manufacturers of isotretionin have entered into an agreement with Covance, a drug development services company that currently coordinates the registry for Celgene's thalidomide. Covance's task is to develop and operate a universal enhanced RMP by mid 2005; this program will require patients, dispensing pharmacists, and prescribers to register in a single, centralized clearinghouse. The program will also mandate that a pregnancy test be performed at certified laboratories instead of home or in-office testing. According to the Accutane RMP, System to Manage Accutane Related Teratogenicity, when the registry denies an authorization to fill the prescription, the prescribing physician must explain the reason for denial to the patient; FDA specifically states that the physician is responsible for informing a woman if a pregnancy test result comes back positive.

Palladone

Due to Palladone's (hydromorphone hydrochloride) high potential for abuse and respiratory depression, the drug's manufacturer, Purdue Pharma LP, in conjunction with FDA, developed an RMP for this new extended-release analgesic. Introduced to the market in January 2005, Palladone is approved for the management of persistent, moderate to severe pain in patients requiring continuous, around-the-clock analgesia with a high potency opioid for an extended period of time (weeks to months) or longer. Palladone is to be used in patients who are already receiving opioid therapy, who have demonstrated opioid tolerance, and who require a minimum total daily dose of opiate medication equivalent to 12 mg of oral hydromorphone.

The analgesic's RMP was devised with four goals:

1. Facilitation of proper use (patient selection, dosing)
2. Avoidance of pediatric exposure
3. Minimization of abuse, and
4. Reduction of diversion

Palladone's RMP includes provisions for understandable and appropriate labeling, and proper education of health care professionals, patients, and caregivers. In addition, the manufacturer has offered training sessions to its sales representatives. The RMP provides for the observation and surveillance of abuse and, if abuse, misuse, and/or diversion occur, this program includes an array of interventions. A Medication Guide will be distributed to patients prescribed Palladone.

During the initial 18 months of Palladone's release to the market, the manufacturer will only promote Palladone to a limited number of medical practitioners experienced in prescribing opioid analgesics and will closely monitor and gather data on Palladone's use and any incidences of abuse or diversion, and report this information to FDA on a regular basis.

Metronidazole and Metformin: Names Too Close for Comfort

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

A family practice physician in a community health center prescribed metformin 500 mg b.i.d. to a newly diagnosed diabetic man from India who did not speak English. When the patient returned to his office a few months later, he brought his medications with him, as requested. His physician quickly noticed that metformin was missing. Instead, the patient had a prescription bottle labeled as metronidazole with directions to take 500 mg twice a day. The prescription had been refilled several times. Luckily, the patient's diabetes remained stable, and he seemed to suffer no adverse effects from two months of unnecessary antimicrobial therapy. The physician notified the pharmacy of the error and asked the pharmacist to check the original prescription, which had been written clearly and correctly for metformin. Upon further investigation, the pharmacist found that the computer entry screen for selecting these medications included "METF" (for metformin) and "METR" (for metronidazole). Apparently, one of the pharmacy staff members had entered "MET" and selected the wrong medication that appeared on the screen.

In another community pharmacy, the same mix-up happened twice, one day apart. In one case, metformin was initially dispensed correctly, even though the prescription had been entered incorrectly as metronidazole – again, when the wrong mnemonic was chosen. The pharmacist who filled the prescription clearly understood that the physician had prescribed metformin, so he filled the prescription accordingly. However, he failed to notice the order entry error, as he did not compare the prescription vial label to the drug container label. Unfortunately, the initial order entry error led to subsequent erroneous refills of metronidazole, as stated on the label. In the other case, bulk containers of the medication were available from the same manufacturer, both with similar highly stylized labels. Thus, confirmation bias contributed to staff 's selection of the wrong drug. After reading "MET" and "500" on the label, the staff member believed he had the correct drug.

In a hospital pharmacy, metronidazole 500 mg and metformin ER 500 mg were accidentally mixed together in the metronidazole storage bin. This resulted in dispensing metformin instead of metronidazole. Fortunately, a nurse recognized the error before giving the patient the wrong medication. Both were generic products, although the brands Flagyl® (metronidazole) and Glucophage®

(metformin) are also available. Unit-dose packages of these drugs contain bar codes, and the printed information is very small, which adds to their similar appearance.

Metronidazole-metformin mix-ups could be serious, considering the different indications and the potential for drug interactions. To avoid selecting the wrong drug from the screen, consider programming the computer to display the specific brand names along with the generic names whenever the "MET" stem is used as a mnemonic. To reduce similarity of the containers, purchase these medications from different manufacturers. Another option in hospital settings is to stock only the 250 mg tablets of metronidazole, since metformin is not available in that strength. This option allows a small risk for nurses who may administer just 250 mg when 500 mg is prescribed, but the potential for harm from giving the wrong drug is greater.

It is also a good idea to separate the storage of these products. During the dispensing process, drug names listed on written prescriptions and hospital orders should be matched to computer labels and manufacturers' products. Since metformin is used to treat a chronic condition, and metronidazole is more likely to be used for an acute condition, outpatient refills for metronidazole are less common and, therefore, bear a second look. Asking physicians to include the drug's indication on the prescription can also help prevent errors.

We have asked FDA to add these drugs to the list of nonproprietary names that would benefit from using "Tall Man" letters. Meanwhile, underline or highlight the unique letter characters in these drug names to make their differences stand out.

'Dietary Supplements' Contain Undeclared Prescription Drug Ingredient

In early November 2004, Food and Drug Administration (FDA) cautioned the public about the products Actra-Rx and Yilishen, which have been promoted via the Internet. These products, purported as "dietary supplements" to treat erectile dysfunction and enhance sexual performance, were actually found to contain the active prescription drug ingredient, sildenafil, the active drug ingredient in Viagra®, which is approved in the United States for the treatment of erectile dysfunction.

The *Journal of the American Medical Association* (*JAMA*) published a research letter that explained the results of a chemical analysis that found that Actra-Rx contained prescription strength quantities of sildenafil. FDA conducted its own analysis, the results of which corroborated the analysis published in *JAMA*.

Sildenafil is known to interact with a number of prescription medications. For example, sildenafil may potentiate the hypotensive effects of medications containing nitrates, which are commonly used to treat congestive heart failure and coronary artery disease.

FDA instructed those who are taking Actra-Rx and/or Yilishen to stop and consult their health care provider and warned that the use of these products could be dangerous to patients' health.

For more information, please visit the following Web site: www.fda.gov/bbs/topics/ANSWERS/2004/ANS01322.html.

NABP Releases Criteria for National Specified List of Susceptible Products, Adds One Drug to List

In late 2004, the National Association of Boards of Pharmacy® (NABP®) Executive Committee finalized the criteria that detail standards and guidance for NABP's "National Specified List of Susceptible Products" (List) based upon recommendations made by NABP's National Drug Advisory Coalition (NDAC). Also, in accordance with NDAC's recommendation, the Executive Committee decided to include Viagra® (sildenafil) on NABP's List. NABP's List, which the Association first released in early 2004, was created to help states reduce redundancy and represented a starting point for states that had an imminent need for such direction. In addition, by adopting NABP's List, states collectively would be able to recognize one national list instead of potentially 50 different lists.

The NDAC is a standing committee that was appointed by NABP's Executive Committee in accordance with the updated Model Rules for the Licensure of Wholesale Distributors, which is a part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. The Model Rules were released by the NABP Task Force on Counterfeit Drugs and Wholesale Distributors, with the aid of representatives from the pharmacy profession, government, and the wholesale distributor industry, to protect the public from the ill effects of counterfeit drugs and devices. In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products."

The updated "National Specified List of Susceptible Products" is available on NABP's Web site at www.nabp.net. NABP's List criteria that detail standards and guidance (eg, under what circumstances a product will be considered for addition to NABP's List) are also available on the Association Web's site and detailed in the February 2005 *NABP Newsletter*.

FDA Announces New CDERLearn Educational Tutorial

The US Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) recently announced that its new online educational tutorial "The FDA Process for Approving Generic Drugs" is now available at http://www.connectlive.com/events/genericdrugs/.

This seminar provides viewers with an overview of FDA's role in the generic drug process. The tutorial also discusses various aspects of the Abbreviated New Drug Application (ANDA) process, including how FDA's approval assures that generic drugs are safe, effective, and high quality drug products.

This program meets the criteria for up to one Accreditation Council for Pharmacy Education contact hour (or 0.1 CEU).

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American Society of Health-System Pharmacists, the Illinois Council on Health-System Pharmacists, the Michigan Pharmacists Association, and NABP.

Some confusion has recently arisen, which needs to be addressed. **All** technicians who have met requirements of the Board are required to register and re-register (every two years). There are many technicians who have achieved PTCB certification, either before or after being registered by the Board, but **all** are required to re-register with the Board. Practicing as a pharmacy technican without a current license places your registration at risk and may jeopardize your future.

To reiterate, Board regulations at 247 CMR 8.07 (2)(a),(b) require that "Pharmacy technician registrations expire every two years on the birthdate of the registrant. A pharmacy technician registration must be timely renewed to continue [to] practice as a pharmacy technician." Board regulations at 247 CMR 2.00 define a Certified Pharmacy Technician as a pharmacy technician who is **currently registered** by the Board and certified by a Board-approved certifying body. **Registration is mandatory, certification is optional** (but strongly recommended).

5. Board Adopts New Regulations to Improve Patient Outcomes

On January 14, 2005, regulations became effective that will require all pharmacies operating in Massachusetts to establish "Continuous Quality Improvement (CQI) Programs" by December 31, 2005. These regulations may be found on the Board's Web site at: www.mass.gov/dpl/boards/ph/cmr/24715.htm.

These mandated programs will require each pharmacy to establish a CQI program "for the purpose of detecting, documenting, assessing and preventing Quality-Related Events (QREs)." At a minimum, a CQI program shall include provisions to designate an individual or individuals responsible for monitoring CQI program compliance with the requirements of 247 CMR 15.00; identify and document QREs; minimize impact of QREs on patients; analyze data collected in response to QREs to assess causes and any contributing factors; use the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs; and provide ongoing professional education at least annually in the area of CQI to pharmacy personnel. The Board encourages anyone with questions about how to establish a CQI program to contact the Board's CQI Coordinator, Leo McKenna, RPh, PharmD, at leo.mckenna@state.ma.us.

Additional Regulation Changes

- Electronic compendia and regulations will be allowed to replace hard copy versions, provided the pharmacy has Internet access and provided further the compendia selected by the pharmacist are updated quarterly. In addition, the compendia may be selected by the pharmacist, provided such are consistent with patients being served by the pharmacy. See www.mass.gov/dpl/boards/ph/cmr/24706.htm#6.02.
- The pharmacist manager-of-record is no longer required to sign a pharmacy renewal application or change in manager application. This may now be done by an "authorized representative" of the company. See www.mass.gov/dpl/boards/ph/cmr/24706.htm#6.02.
- A pharmacy must provide a designated consultation area, with signage stating "Patient Consultation Area," designed to provide adequate privacy for confidential visual and auditory patient counseling. The private consultation area must be accessible by the patient from the outside of the prescription dispensing area without having to traverse a stockroom or the prescription dispensing area. This shall be effective for all new or relocating pharmacies on April 1, 2005. All existing pharmacies must comply with 247 CMR 6.01(5)(d) by January 1, 2007. See www.mass.gov/dpl/boards/ph/cmr/24706.htm#6.03.
- Allows a certified pharmacy technician to transfer a Schedule VI medication refill upon request by a consumer. See www.mass.gov/dpl/boards/ph/cmr/24709.htm#9.02.
- Allows foreign pharmacy graduates, who have received authorization from NABP to sit for the Foreign Pharmacy Graduate Equivalency Examination®, to register for internship, provided the authorization was issued within the preceding year. See www.mass.gov/dpl/boards/ph/cmr/24708.htm#8.01.

6. Responding to an Error

By Sophia Pasedis, PharmD, RPh, Secretary

The Board of Registration in Pharmacy reviews all aspects of a medication error in matters that come before the Board. Of particular importance to the Board are the actions taken after a medication error is identified. How you respond to an error, in fact, can be a crucial factor in your professional career.

First and foremost, **listen to your patients**. If a patient makes a statement that just does not seem right in relation to his or her medication, a red flag should immediately go up. Stop what you are doing and promptly investigate his or her concern. Too often the Board has seen mistakes escalate and cause patients harm simply because the pharmacist did not take the time to listen and investigate the concern. For example, a patient may say, "This pill does not look like the same one I took last time." The pharmacist may incorrectly assume the patient had previously taken the generic version and dismiss the comment. What the pharmacist should do is compare the medication with what is on the shelf or check the medication markings on Identidex. Dismissing the comment without investigation may save time in the short term and allow you to get back to work, but it is clearly not in the patient's best interest or yours if an error results. Any opportunity to affirm the accuracy of a prescription prior to dispensing should be taken due to the great likelihood of the negative results to

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the patient and to your professional career.

The Board also notes the importance of acknowledging the error to the patient after the error has been identified. Taking responsibility for the error and discussing the matter with the patient is the ethical and appropriate response to the patient. Attempting to cover up or deny that an error has occurred will not be viewed favorably by the patient or the Board. The patient will appreciate an explanation of the error and assurance that appropriate action will be taken to prevent the recurrence of a similar error in the future.

Remember, always **keeping the best interest of the patient paramount** in your decision making is in your best interest as well. Make sure you ask plenty of questions to determine if further medical intervention is needed. Advising the prescriber of the error is also recommended. Following up with the patient the next day to make sure he or she is feeling well as well as the next time you see the patient further demonstrates your concern for the patient.

The final and crucially important step in responding to a medication error is identifying any system changes necessary to prevent the recurrence of various types of errors. Recently, promulgated Board regulations (247 CMR 15.00) require pharmacies to establish **CQI programs** to provide for information sharing with all pharmacy staff. The Board recommends the implementation of a reporting system in each pharmacy that includes organization-wide information sharing, employee feedback, and continuous improvement.

We need to train ourselves to continuously strive to improve our practices each day. Implementation of CQI in all pharmacy settings will reduce errors, keep patients safe, and improve our performance as professionals.

No pharmacist wants to make an error. In many instances, the systems are the culprit. It is important that you speak up and let your manager-of-record know the deficiencies in your systems. It takes a team to make a system work. Please become familiar with the new CQI program regulations and take an active role in assuring patient safety and minimizing the risk of complaints regarding your license.

7. Reconsidering Reconstitution

By Leo McKenna, RPh, PharmD, CQI Surveyor

In recent months there have been several QREs involving reconstituted products reported to the Board. The specific reconstituted suspensions involved include amoxicillin, Augmentin®, Cefzil®, and Zithromax®, but could have been any product that requires reconstitution. The above products were alleged to have been reconstituted with half the required diluent. The preparations were all verified and dispensed with improper concentrations as labeled on the prescription. As a result, the prescriptions were all concentrated to twice the labeled strength and ingested by pediatric patients. Some of the patients experienced side effects including nausea and vomiting that required follow-up treatment from their respective pediatricians. The QREs had a common prescription processing error that involved the reconstitution technique of filling the prescription bottle halfway with the diluent, shaking the contents until dissolved, and adding the remaining amount of diluent. The common error or root contributor to the QRE was pharmacist distraction during the preparation of the suspension. Due to the frequency of these QRE reports, the Board recommends that the pharmacist add a "thinking step" when preparing a reconstituted product that allows for a **double-check** of the volume of medication being dispensed. Eliminating any type of diversion or distraction during the suspension preparation process may prevent future errors from occurring. A suggestion to manufacturers would be to furnish a calibrated bottle to eliminate filling errors. This would act as a double-check system for the pharmacist on the product end, providing a set "fill-to" line. The implementation of a definitive product bottle and pharmacist awareness of the problem will result in fewer errors in the reconstitution of suspensions.

Everyone should be reminded that the Board finds the increase in pediatric and other age-related errors to be particularly concerning and cannot emphasize enough how important it is to patient safety and optimized care to provide counseling each time an age-related prescription is dispensed.

Please consider providing feedback to the Board about your comments/suggestions about this and future *Newsletters*. Remember, this *Newsletter* is for you, so feel free to send recommendations for future *Newsletters* by e-mail to charles.young@state.ma.us or james.d.coffey@state.ma.us.

8. Massachusetts Professional Recovery Program

Licensed professionals reaching out to help other licensed professionals cope with alcohol and drug problems.

If you or someone you know has, or you suspect may have, a substance abuse problem, please read the following information closely:

The Massachusetts Professionals Recovery System (MPRS) is a public-private partnership between the Commonwealth of Massachusetts Division of Health Professions Licensure and various professional societies and organizations, established to assist state-licensed professionals with alcohol and drug problems.

The program is designed to protect public safety and uphold a high standard of professional practice by monitoring the recovery of Board licensees with alcohol and drug problems. The MPRS provides an appropriate framework to encourage licensees with alcohol and drug problems to seek recovery without disciplinary action (for those who choose to self-report).

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What We Believe

Chemical dependency is a bio-psychosocial disease affecting the cognitive, emotional, spiritual, and physical well-being of the individual. It is a chronic, progressive health problem that responds positively to intervention and treatment. Behavioral change is possible and every professional should have the right to pursue recovery.

Recovering professionals make vital contributions to society. Given appropriate adaptations and accommodations, professionals in recovery can safely continue or resume practice in their communities.

MPRS, in its attempt to confidentially help professionals in need, understands that it must also protect and safeguard the public.

How We Work

A licensed professional admitted to the MPRS program agrees to abide by a prescribed treatment plan and contract developed by the MPRS Advisory Committee. The individual is supervised and monitored by the MPRS staff and Advisory Committee.

Noncompliance with the treatment contract may constitute grounds for reporting a participant to the appropriate board of registration and may be cause for disciplinary action by that board.

Admission to the program will be considered when an individual agrees to attempt to abstain from the use or abuse of mood-altering drugs and alcohol.

The MPRS encourages self-referrals of professionals with alcohol and drug problems.

For additional confidential information please contact MPRS Coordinator Tim McCarthy at 617/727-2880 or visit the MPRS Web site at www.mass.gov/dpl/services/mprs.htm.

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